K052372

SEP 22 2005

510(k) Summary

Date Prepared: August 24, 2005

Submitter:
Medtronic Perfusion Systems
7611 Northland Boulevard
Brooklyn Park, MN 55428

Contact Person:
Ronald W. Bennett
Principal Regulatory Affairs Specialist

Phone: (763)-391-9086
Fax: (763) 391-9603

Device Name and Classification:

Trade Name: **MC2X™ Multi-Stage Venous Cannula**

Common Name: **Cardiopulmonary bypass vascular catheter, cannula or tubing**

Classification: **Class II**

Predicate Devices: **MC2X™ Multi-Stage Venous Cannula**
K031776

Device Description:
The MC2X™ Multi-Stage Venous Cannulae are cannula with wire wound bodies with side ports in the distal tip, with ported atrial basket drainage and with an approximate overall length of 15 ¼". Insertion depth marks aid in positioning the cannula. All are supplied sterile, are non-pyrogenic and are single use. The devices may include a Carmeda® coating. They also include an extended length version with tubing attached with a quick disconnect.

Indication for Use
This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery.

Comparison to Predicate Device
The predicate devices are Two Stage Venous Cannulae with the same general design characteristics. The predicate 510(k) devices currently marketed have the same indications for use. The predicate devices also provide drainage of the vena cava at the tip and provide atrial drainage. The new models have a change to the size of the drainage basket, a slight change to the shape of the tip, and a three piece rather than one piece construction.

Summary of Performance Data
Qualification including visual inspection, collapse, flow, kink and tensile testing were conducted on devices. Sterilization and accelerated aging was used to qualify the devices.

Conclusion
Medtronic Perfusion Systems has demonstrated that the modified MC2X Multi-Stage Venous Cannulae are substantially equivalent to the predicate devices based upon design, test results, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 2 2005

Medtronic Perfusion Systems
c/o Mr. Ronald W. Bennett
Principal Regulatory Affairs Specialist
7611 Northland Drive N
Brooklyn Park, MN 55428

Re: K052372
MC2X™ Multi-Stage Venous Cannula
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary Bypass Catheter, Cannula, Tubing
Regulatory Class: II
Product Code: DWF
Dated: August 26, 2005
Received: August 30, 2005

Dear Mr. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052372

Device Name:

MC2X™ Multi-Stage Venous Cannula

Indications for Use:

This cannula is intended for use in venous drainage via the right atrium and inferior vena cava simultaneously during cardiopulmonary bypass surgery.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052372